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EXAMINER

VALENROD, YEVGENY

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

12/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/579,033

Applicant(s)

DUNKEL ET AL.

Examiner

YEVEGENY VALENROD

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3 is/are allowed.
- 6) ☒ Claim(s) 4-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The following is a second non-final office action in application # 10/579,033. This application has been transferred to Examiner Valenrod whose contact information is provided at the end of the instant document.

Applicants Remarks have been fully considered and rejection of claims 1, 2 and 4 under 35 USC 103(a) is withdrawn.

Declaration of Ulrike Wachendorff-Neumann has been fully considered. Of particular relevance were examples A.45 and Ex.8 presented in the declaration on page 5. The said examples demonstrate the increase in efficacy using instantly claimed compounds. Rejection of claims 1,2 and 4 under 35 USC 103(a) is withdrawn.

The restriction requirement between compound of claims 1, 2 and 4 and the methods of claims 3, 5-7 is withdrawn. Claims 3 and 5-7 are rejoined and are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-7 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for controlling unwanted microorganisms where the

organism is selected from *Puccinia recondita*, *Sphaerotheca fuliginia* and *Venturia inaequalis*, does not reasonably provide enablement for controlling *any* unwanted microorganism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the invention and Breadth of the claims:

Claims 4 and 7 are directed to a composition and a method of preparing a composition wherein the said composition has an intended use of controlling unwanted microorganisms. Although the composition itself is deemed novel, the claimed intended use is not enabled for the full scope of the said use.

Claims 5 and 6 are directed to a method of controlling unwanted microorganisms by applying the composition of claim 4.

Breadth of claims in the instant case arises directly from the scope of the microorganisms that the applicant claims to control. the term "unwanted microorganism" does not have a limiting definition in the specification and therefore includes hundreds of thousands of microorganism including those for which no pharmaceutical method of control has been recognized, such as for example the Ebola virus. The breadth of claims 4-7 is therefore extremely broad.

State of the prior art and level of predictability in the art:

Since compounds of claim 1 have been deemed novel the art is silent as to their ability to control unwanted microorganisms. One skilled in the art can not predict which microorganisms can be controlled by using applicants claimed composition. The only way to find out if a given compound has an effect on a microorganism is via experimental method.

Amount of direction provided by the inventor and existence of working examples:

Inventors provide Examples where compounds representing full scope of compound of formula (I) are evaluated for their ability to control *Puccinia recondita*, *Sphaerotheca fuliginea* and *Venturia inaequalis* (Examples A, B and C pages 34-41). Applicant is clearly enabled for controlling the above three microorganisms. As far as controlling the hundreds of thousands of microorganisms encompassed by the term "unwanted microorganisms" applicant only states an intent to do so but provides no actual examples.

Relative skill of those in the art and quantity of experimentation needed to make or use the invention:

The quantity of experimentation required for practicing the full scope of applicants' invention is immense. One skilled in the art would have to devise a testing regimen for each of the hundreds of thousands of microorganisms and test each one with the composition comprising the compound of formula (I). Numerous tests would have be performed as the concentration of the active ingredient required to produce a positive result (if there is any) will invariably differ from one microorganism to another. The above testing amounts to millions of experiments which can certainly be construed as undue experimentation.

Thus, given these considerations, one of ordinary skill in the art clearly would not be able to practice the claimed method such that it can be used as contemplated in the specification without first engaging in substantial and undue experimentation. Therefore, the claims are rejected under 35 U.S.C. §112, first paragraph, as lacking an enabling disclosure.

Note:

One way to overcome the rejection of claims 4 and 7 can be overcome by removing the intended use from the claim language.

Allowable subject matter

Claims 1-3 are allowed.

Conclusion

Claims 1-7 are pending

Claims 1-3 are allowed

Claims 4-7 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yevgeny Valenrod/

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Primary Examiner, Art Unit 1621

Application/Control Number: 10/579,033
Art Unit: 1621

Page 7